Remarks

Specification

The Abstract was objected to because it was incomplete. A new abstract is submitted in lieu of completing the original abstract because the present claims are method claims and the original abstract referred to an apparatus.

Claim Objections

Claim 10 was objected to because of informalities involving commas. Claim 10 has been amended by placing a comma appropriately.

Claim 16 was objected to because it refers to a non-elected claim (Claim 1). The content of Claim 1 has been added to Claim 16. Claim 16 was also objected to with respect to commas in the portion added from Claim 1. Commas have been added.

Claim Rejections, Section 112

Claim 12 was rejected under Section 112 on the basis that "it is not clear what the apparatus the Applicant wishes to secure to the positioning ring to in Claim 12." Claim 12 has been cancelled.

Claim 16 was rejected on the basis that respecting lines 12-15 of Claim 1, it is not clear what apparatus are moving away from the drive mechanism and what apparatus are moving toward the drive mechanism. This rejection is traversed.

The claim has been amended to recite the structure of claim 1 and that the operation is place the drive mechanism on the temporal side of the positioning ring and the blade on the nasal side of the positioning ring and drawing the blade toward the drive mechanism so as to make a corneal flap with a temporal hinge, that is, a hinge on the temporal side of the flap.

Claim rejections, Section 102(b).

Claims 10-12 were rejected under section 102(b) over Hellenkamp. This rejection is traversed.

Claim 10 has been amended to more clearly define the invention as providing a drive mechanism placed on the temporal side of the eye and the

blade in a starting position on the nasal side of the eye. Then, in operation the drive mechanism draws the blade, which is facing the drive mechanism, toward the drive mechanism, from the nasal side of the eye toward the temporal side of the eye, to create a flap that has a temporal hinge.

The Hellenkamp mechanism creates a corneal flap by cutting along an arcuate path (4:41). This is accomplished by a cutting head assembly 50 and a coupling member 90 being mounted on a pivot shaft 44 which is upstanding from the positioning ring 32. This causes the cutting head assembly 50 to pivot across the positioning ring 32 along an arcuate path (9:55). The cutting element 70 is housed in the in the cutting head assembly 50, so the cutting head cuts with a pivoting motion. There is a stop means 65 to stop the cutting action. But, there is no description of the shape of the cutting element, so it is not possible to determine the shape of the "flap". Also, referring to Figs 10A and 10B and also Fig 8 and Figs 5A-C, it is not clear to Counsel what exactly is the cutting path and where the open portion and where the flap are located. For example in Fogs 10A and 10B, where is the cutting element; where does the cut start and where does it end? This information is not available from the figures or the description.

Therefore it is submitted that Hellenkamp does not teach the method of claim 10 in which a blade is drawn linearly toward the drive mechanism, from a nasal position across the cornea toward the temporal side and stops leaving a temporal flap.

Regarding claims 11 and 12, the forgoing is applicable.

<u>Claim rejections Section 103.</u>

Claim 13 was rejected under section 103 as being obvious over Hellenkamp as applied in further view of Steinert. This rejection is traversed.

Although Steinert discloses use of a sapphire blade, as commented above, Hellenkamp does not disclose the cutting device configured to allow a corneal flap with a temporal hinge.

Claims 14 and 15 were rejected under section 103 over Hellenkamp as applied to claim 10, in further view of Ross. These rejections are traversed.

In claim 14 there are two spaced apart elements with the guide and the blade attached at lateral extremities to them to define the substantially fixed relationship of the guide to the blade. This is explained in the specification first with reference to the structure of Figs 6, 9a and 9b in which the blade fork assembly 60 has forks 68 and the guide 70 and blade 66 are both attached to the forks 68. Similarly, for the configuration now claimed the forks 214 and 216 have the blade 208 and the guide 212 attached to them. By attaching both the blade and the guide to the same elements, the spaced apart forks, greater precision in their relative positioning can be achieved, which is important in the precision surgery of making a corneal flap. Then, as the blade assembly moves linearly, the guide and the blade work together to make a precision flap.

First as to Ross, the device described has two drive mechanisms, one for a first movement and the other for a transverse movement. A ring 12 is placed onto the cornea. It has an opening 18. A blade 16 is located within the opening 18. The blade 16 can move within the opening 18 in both the first and transverse directions, simultaneously. The blade is attached to a blade holder 20 which is attached to a head 22... These move relative to the ring. The blade holder 20 moves in the second direction while being pulled in the first direction. But, the head only moves in the first direction. As seen in fig 5, each lower edge of the head 22 may have a dovetail shape to cooperate with slots 26 in the ring 12. This prevents movement of the head 22 in the second direction while allowing movement in the first direction. There is a first drive mechanism 28 that moves the head, the blade and the holder in the first direction. With this somewhat mysterious movement description, it seems that the first movement is forward across the ring causing the cutting and the second movement is at an angle, downward to set the depth of the cut. Notably, the blade 16 can move relative to the plate 19, by which the spacing between them can vary. The plate 19 is suspended between what appear to be legs, part of the head 22. But the blade is not on those legs, nor fixed in relation to them, since the legs can only move forward, while the blade can move both forward and downward.

So, the Ross arrangement does not replicate the blade assembly claimed in which the blade and the guide are fixed relative to each other on the forks.

Then comes the question of how the Ross structure could be adapted to the Hellenkamp structure, and what would be the resulting structure. First, there is no way to adapt the Ross structure to Hellenkamp. They are different in numerous respects. Hellenkamp has an arcuate movement with a blade that seems to just project from a holding device downwardly. Its shape is not revealed but it does not appear to extend to any spaced apart holding device. How such a device would be implemented in Hellenkamp is a mystery, but seems to be impossible because the Hellenkamp blade has to move sideways in an arcuate path, so it has to be able to cut on a sideways motion...

Of course, any possible adaptation of Ross to Hellenkamp would not result in the presently claimed device in claim 14.

Claim 15 makes the guide integral to the spaced apart elements (the forks). This is important to keep the relative spacing of the guide and the blade as consistent and precise as possible. That relation ship has no relevance to Hellenkamp, and is contrary to Ross in which there is relative movement between the blade and the plate.

Claims 16 and 17 were rejected under section 103 over Ross in view of Ophthalmology Times. This rejection is traversed.

Ross is described above and it inapplicability is the same. OT simple says that there can be a temporal hinge. The invention does not claim to have discovered the concept of a temporal hinge. The Examiner has not explained how one would vary or use Ross to make a temporal hinge, but in any case the mechanism is quite different from that claimed as described above.

With the foregoing it is submitted that the claims are in allowable condition. If the Examiner has any questions or further issues, he is invited to call the undersigned to conveniently resolve them.

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